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TITLE: Self Managing the Consequences of Major Limb Trauma

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14. ABSTRACT The objective of this research is to develop and evaluate the efficacy of a computer-based self management program (heretofore referred to as OSMP-T) for reducing secondary conditions and improving function following major lower limb trauma. The intervention will build on widely accepted self-management programs developed for persons with arthritis as well as components of a face-to-face self-management program for civilians with long-standing limb loss. It will be necessary, however, to tailor the content and delivery of these programs to better accommodate the needs of a young, acutely injured population. Specific needs not typically addressed in the existing programs include the management of acute anxiety and post-traumatic stress disorder (PTSD), and the maintenance or acquisition of employment or return to active duty. The specific aims of the proposed study are three-fold: (1) to develop the OSMP-T; (2) to evaluate the efficacy of the OSMP-T in 225 civilians initially treated at 5 level I trauma centers; and (3) to modify the OSMP-T for application in the military and to pilot the modified program in a smaller group of 24 injured soldiers treated at the Walter Reed Army Medical Center. If shown to be efficacious, computer based self management programs for the acutely injured will provide a much-needed adjunct to the orthopedic care now available and contribute to a comprehensive trauma management program to improve long-term outcomes and quality of life. The military version of SM program will provide injured soldiers with an ongoing mechanism of support as they transition from inpatient rehabilitation to the community – whether that be in the military or

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Self-Managing the Consequences of Major Limb Trauma
Annual Report

March, 2007

INTRODUCTION. The objective of this research is to develop and evaluate the efficacy of a computer-based self management program (heretofore referred to as OSMP-T) for reducing secondary conditions and improving function following major lower limb trauma. The intervention will build on widely accepted self-management programs developed for persons with arthritis as well as components of a face-to-face self-management program for civilians with long-standing limb loss. It will be necessary, however, to tailor the content and delivery of these programs to better accommodate the needs of a young, acutely injured population. Specific needs not typically addressed in the existing programs include the management of acute anxiety and post-traumatic stress disorder (PTSD), and the maintenance or acquisition of employment or return to active duty. The specific aims of the proposed study are three-fold: (1) to develop the OSMP-T; (2) to evaluate the efficacy of the OSMP-T in 225 civilians initially treated at 5 level I trauma centers; and (3) to modify the OSMP-T for application in the military and to pilot the modified program in a smaller group of 24 injured soldiers treated at the Walter Reed Army Medical Center. If shown to be efficacious, computer-based self-management programs for the acutely injured will provide a much-needed adjunct to the orthopedic care now available and contribute to a comprehensive trauma management program to improve long-term outcomes and quality of life. The military version of the SM program will provide injured soldiers with an ongoing mechanism of support as they transition from inpatient rehabilitation to the community – whether that be in the military or civilian sectors.

BODY OF THE REPORT: ACCOMPLISHMENT OF YEAR ONE TASKS: Eight tasks were proposed for Year 1 of the project. These tasks relate to the first specific aim of the research, namely the development of the OSMP-T intervention. For several reasons, we have been delayed in completing some of these tasks:

First, after initial piloting of the face to face version of the self-management (SM) program we realized that significant revision to its scope and content was needed (especially to accommodate the needs of those individuals who had sustained a mild traumatic brain injury together with their major lower limb injury). For this reason we spent the first few months of the project period revising these lessons.

Second, we significantly underestimated the time required to translate the 9 SM lessons to the web. We have made significant progress in this regard after spending the first few months looking into existing programs with goals comparable to that of the OSMP-T. After much discussion with various IT firms we also decided to do the upfront programming in-house so that we can maintain better control over the direction of the OSMP-T. After developing a prototype lesson which is acceptable to users, we will re-consider the use of an IT firm to complete the programming for the remainder of the lessons.

Third, we had delays obtaining IRB approval from the Carolinas Medical Center. While this delay has affected our ability to conduct an initial focus group (before finalizing the content of the lessons and developing the basic approach to their translation to the

web), it has not affected our ability to use Carolinas as the site for 1-2 rounds of usability tenting.

These delays will not significantly impact our ability to accomplish the work initially outlined in the 3-year protocol. The only change will be the inability (within the 3-year time frame) to conduct the 6 month evaluation on the third cohort of participants. We will, however, have 3 month evaluations on all participants in the study. We have revised our timeline and include it here as **Appendix 1**.

Below we review the status of each task for Year 1 as outlined in our original Statement of Work:

Task #1: Develop Lesson Content. This task has been completed. The lesson content was originally developed and piloted (in person, face to face) in collaboration with the American Trauma Society (with seed funding made available through our Center for Injury Research and Policy). When we piloted the lessons in a group, face to face venue we discovered several shortcomings of the content. Specifically we found the need to reduce the amount of content and alter its presentation somewhat to better accommodate the needs of participants who had sustained a mild traumatic brain injury (TBI). Although the intervention is NOT designed to be used with individuals with a major TBI, given the high prevalence of mild TBI (among those sustaining major limb trauma), we decided to design the intervention with this group in mind. All nine lessons have now been revised and are ready to be translated to a web format.

Task #2 Establish a Scientific Advisory Committee. This task is completed. The Committee met to discuss the content of the lessons and the translation of the material to the web. We also decided to establish a separate *Consumer Advisory Committee* consisting of 5 individuals who have sustained an injury and who participated in the face to face self-management pilot at Inova Fairfax Hospital. These individuals will work closely with the investigators in reacting to various components of the web based program and will assist us in assuring it meets the needs of the consumer. This committee will meet face to face 1-2 times over the next year. However, the majority of the communication with the Consumer Advisory Committee will be via the web and telephone conferencing.

Task #3: Conduct Focus Group # 1. Due to delays in obtaining IRB approval from Carolinas Medical Center we have decided *not* to conduct this initial focus group. The purpose of the group was to obtain input on the content of the self-management lessons and to ascertain preferred computer based learning methods. We decided that we had obtained sufficient input on the lesson content (through the pilot described above). Our consultant, Cari Wolfson of *Focus on U!* has extensive knowledge on preferred computer based learning methods and her experience will continue to inform the translation of the lessons to the web. In addition, we are using our Consumer Advisory Committee (see above) to provide feedback on several of the approaches we are using to engage participants in the OSMP-T.

Task #4: Develop Library of On-Line Resources. A first draft of the resource library has been developed. We are currently in the process of having this material reviewed by experts in specific content areas and placed on the web.

Task #5: Translation of Lesson Content to Web-based Application. The lesson content will be delivered using interactive Flash presentations. A total of 18 half hour Flash presentations will be produced. The content for all presentations has been completed (see Task # 1). The Flash platform was chosen based on its high level of market penetration (greater than 98% in the U.S.A.), ease of integration with optional audio and video content, the possibility of using low bandwidth / high quality animated vector graphics, compatibility with PHP and SQL, and the availability of well developed user support groups.

A protocol has been developed for the translation of lesson content to Flash. The backbone of each lesson is created from two basic files: a slide presentation and the narrator's audio script. The slide presentations can then be readily converted to Flash using Macromedia Captivate. Similarly, the audio scripts can be translated into audio files using recording facilities available in house. We anticipate having all 18 half hour sessions scripted within the next 6 months. Once the backbones for each session are created, interactive components are added to each one. A modular development approach has been used for these interactive components, since all interactions conform to one of three input patterns and two feedback patterns. The input patterns are: 1) the user responds to questions by clicking on one of a limited set of options (such as true/false, multiple choice, or Likert scales); 2) the user checks all, some or none of a set of items on a checklist; and 3) the user types into a text entry form. The feedback patterns are: 1) user's text or selections are presented to him/her later in the session; and 2) customized content is presented to the user based on earlier input and pre-set response algorithms. All five of these interactive modules are done or near completion. Integrating these code modules into the flash sessions will require minimal programming beyond changing variable names. We anticipate completion of all (roughly 30) situation specific algorithms to be completed within the next couple of months.

A PHP based Learning Management System (LMS) will be used to track user's progress through the course. This LMS (to be completed within the next two months) will record completed sessions and direct users to the correct session, extract completed forms within each session to produce portable PDF workbooks users can print or save to their computers, and send e-mail reminders when users fall behind on the sessions. The LMS is integrated to the website's membership management system to facilitate seamless transitions between lessons, online chats, message boards, and evaluation questionnaires using a single security system.

Task #6: Construct Website and Conduct Usability Testing. As described above, the platform for the website is under construction. Important functionality has been created and tested, including features that allow data entered in response to questionnaires to be used in tailoring later information, message boards, and audio files accompanying slide presentations. We are currently seeking consultants to assist with graphic design. In Months 18-20, we will work with our consultant, Cari Wolfson, to conduct usability testing on the first 2 lessons. This testing will be done with the involvement of individuals recently discharged from Carolinas Medical Center for treatment of a major lower limb injury.

Task # 7: Refine Study Design, Write Manual of Operations. The study design has been refined based on input from our scientific advisory committee. As described in the

original application for funding, the proposed study will use a two group randomized controlled clinical trial design. The two groups are: (1) standard care plus the online self-management program (OSMP-T**)** (*the treatment group*) or (2) standard care supplemented by access to the American Trauma Society's website (*the control group*). The study will examine the short-term effects of the OSMP-T in 225 patients treated at one of five level I trauma centers for a major leg trauma. These 225 individuals will be randomized into the treatment and control groups after they have been consented into the study. Participants in the control group will be given the opportunity to participate in the OSMP-T after the conclusion of the study's evaluation. Outcome data will be collected at baseline (before the start of the intervention), after completion of active treatment, and at 3 and 6 months following the end of active treatment. All assessments for both groups will be administered on-line. These assessments are summarized in Table 1 below:

Table 1: Data to be Collected in Assessing the OSMP-T

Variable	Measure/ Source	From Trauma Registry	At Baseline	At end of Program	At 3 and 6 Months
Primary Outcomes					
Pain	Chronic Pain Grade (CPG) Scale		x	x	x
Depressive Symptoms	Center for Epi. Studies Depression Scale (CES-D)		x	x	x
Anxiety	Spielberger State/Trait Anxiety Scale (STAI)		x	x	x
PTSD	PTSD Checklist (PCL)		x	x	x
Positive Affect	Positive and Negative Affect Schedule (PANAS)		x	x	x
Secondary Outcomes					
Restrictions in Activities and Participation	Short Form Musculoskeletal Func Assessment (SMFA) Return to usual major activity		x	x	x
Quality of Life	Satisfaction with Life Scale		x	x	x
Intermediary Outcomes					
Self-Efficacy	Modified Self-Efficacy Scale		x	x	x
Catastrophizing	Coping Strategies Q (CPSQ)		x	x	x
Readiness to Engage in Self Management	Self-Management Stages of Change Questionnaire		x	x	
Activation	Patient Activation Measure		x	x	
Reach and Implementation/Integrity of the Intervention					

Reach/ Compliance/ Satisfaction	Percent and representativeness of those who agree to participate (of eligible); Number of Sessions Attended; Satisfaction with OSMP-T and ATS Website			x	
Implementation/ Utilization	Number of lessons completed; participation in discussions; posting to bulletin boards; Borkovec's Credibility of Tx Rating			x	
Correlates of Outcomes					
Type/Severity of Injur(ies)	Orthopedic Trauma Registry	x			
Sociodemographic Characteristics	Age, Gender, Race/Ethnicity	x			
Co-morbidities	Charlson Co-morbidity Index	x			
Health Habits	Smoking (frequency/amount); Substance Abuse using AUDIT		x		
Education and Economic Resources	Education, Usual Major Activity, Income, Poverty Status		x		
Social Support	Multidimensional Perceived Social Support (MPSS)		x		

Final criteria for inclusion in the study are:

- ages 18-54;
- one or more lower extremity injuries of sufficient severity, including: grade III tibia fractures, pelvic and acetabular fractures, open distal (supracondylar)femur factures; bicondylar tibia plateau fractures, severe foot, calcaneus and pilon fractures, dysvascular injuries below the distal femur excluding foot; major soft tissue injuries below the distal femur; and traumatic amputations (excluding toes).
- no significant brain injury (i.e. Glasgow Coma Scale Score of 15 at discharge from the hospital);
- no spinal cord deficit;
- English speaking; and
- access to and use of the internet from home.

As we moved forward in preparing the Manual of Operations and obtaining IRB approval from the participating sites (see Task #8 below) we added Katherine Frey to our Research Team. Ms. Frey has extensive experience coordinating multi-center studies. Her biographical sketch is included as Appendix 2.

Task #8: Obtain IRB approval from Participating Centers. We are now in the process of finalizing the selection of study sites, developing Memoranda of Understanding with these institutions and developing intuition-specific IRB protocols (based on model protocol for the study). This process was intentionally delayed until we

were closer to having developed the intervention. Participants include: Carolinas Medical Center in Charlotte NC; Bowman Gray Trauma Center in Winston Salem, NC; Harborview Trauma Center in Seattle, WA; Inova Fairfax Hospital in Fairfax, VA, and either Parkland Hospital in Dallas, TX or Orlando Regional Medical Center in Orlando, Florida. Two trauma centers who originally agreed to participate (Universtiy of Maryland Shock Trauma Center in Baltimore, MD, and Vanderbilt University Trauma Center in Nashville, TN) can no longer participate due to their commitment to another study that would interfere with the evaluation of the OSMP-T. We anticipate receiving final IRB approvals for all study sites by Month 18.

KEY RESEARCH ACCOMPLISHMENTS:

- The in-person, face to face version of the self management intervention was refined to accommodate persons with mild traumatic brain injury;
- Scientific and Consumer Advisory Committees were established to guide development and evaluation of the OSMP-T;
- The OSMP-T website and key interactive modules have been constructed;
- A protocol for translation of the lesson content to Flash has been developed;
- A first draft of the resource library ahs been developed.

REPORTABLE OUTCOMES:

As discussed above, the platform for the website has been developed, but there are no other reportable outcomes.

Based on our work this year, by the end of Year 2, we will have a fully-functioning website and our first cohort of participants will be consented into the study.

CONCLUSION:

Despite some unanticipated delays, including lengthy IRB review processes, and greater time involved in translating face-to-face intervention to online version, we are on track to complete the research before the end of the project period. The only change will be the inability (within the 3-year time frame) to conduct the 6 month evaluation on the third cohort of participants. We will, however, have 3 month evaluations on all participants in the study. With a 3 month no-cost extension (Year 1 spending was lower than anticipated), all 6-month evaluations will be completed. We have revised our timeline and include it here as **Appendix 1**.

If shown to be efficacious, the OSMP-T will also provide a critical component to civilian orthopedic care now available in trauma centers throughout the country and ensure comprehensive trauma management to improve long-term outcomes and quality of life. Traditionally, we have focused on medical interventions to manage the secondary conditions of anxiety, depression and pain following major trauma. There is growing evidence to suggest these interventions may not be sufficient and that cognitive behavioral interventions are critical in sustaining long-term, quality outcomes. The planned SM intervention uses education, self-monitoring, problem solving and skill acquisition to address multiple dimensions of the post trauma experience. Cultivation of self-efficacy, adaptive behavior, coping skills and relapse management strategies will

enable participants to employ learned skills to successfully address the multiple medical and psychosocial problems they encounter post injury.

A key consideration in designing the proposed OSMP-T intervention is the potential for replication and overall cost-effectiveness. Advances in computer technology present the opportunity to develop multimedia, interactive SM interventions that have the potential to reach large numbers of individuals in a cost-effective manner. While there is a growing body of literature that supports the potential cost-effectiveness of such programs, the planned clinical trial utilizing an online SM intervention is critical to establish the efficacy of this class of intervention in persons with acute limb trauma.

This project has direct relevance for the military. Hundreds of young Americans have sustained severe limb injuries in the Iraq and Afghanistan conflicts. Following separation from military service and reintegration into society, disability from injuries will impact these individuals for the remainder of their lives. The military version of SM program we are proposing to develop and evaluate will assist in assuring that these soldiers achieve the highest level of function and quality of life. Development of an online application, in particular, will be cost-effective and provide an ongoing mechanism to provide support for injured soldiers as they transition from inpatient rehabilitation to the community – whether that be in the military or civilian sectors.

REFERENCES: None

APPENDICES: Attached are 2 appendices.

Appendix 1: Revised Timetable (as of March, 2007)

Critical Event	Projected Completion
AIM #1: Develop OSMP-T Intervention	
• Develop and Refine Lesson Content	Completed
• Establish *Scientific Advisory Committee*	Completed
• Establish *Consumer Advisory Committee*	Completed
• Develop Library of On-line Resources	Month 16
• Develop Protocol for Translation of Lesson Content to Flash	Completed
• Construct Website and Key Interactive Modules	Completed
• Develop Learning Management System to Track User's Progress	Month 14
• Script 1st 2 Lessons for Web Presentation	Month 13
• Translate 1st 2 Lessons to Web Based Application	Month 18
• Conduct Usability Testing (2 rounds)	Month 18-20
• Script Lessons 3-9 for Web Presentation	Month 19
• Translate Lessons 3-9 to Web Based Application	Month 20-24
• Incorporate Final Graphic Design	Month 20-24
AIM #2: Conduct Evaluation of OSMP-T in Civilian Population	
• Refine Study Design and Enroll Study Sites	Month 14
• Finalize Outcome Assessment Tools	Month 14
• Obtain IRB approval from Participating Centers	Month 18
• Write Manual of Operations	Month 19
• Pilot Screening and Recruitment Procedures	Month 19
• Recruit and Train Coaches	Month 20-22
• Cohort #1	
• Screen Eligible Patients in Trauma Centers	Month 21-23
• Enrollment and Baseline Assessment	Month 25-26
• Evaluations(immediate post, at 3 and 6 months)	Month 27-32
• Cohort #2	
• Screen Eligible Patients in Trauma Centers	Month 24-26
• Enrollment and Baseline Assessment	Month 28-29
• Evaluations(immediate post, at 3 and 6 months)	Month 30-35
• Cohort #3	
• Screen Eligible Patients in Trauma Centers	Month 27-29
• Enrollment and Baseline Assessment	Month 31-32
• Evaluations(immediate post, at 3 and 6 months)	Month 33-35
• Data Analysis	
• File Development	Month 27-32
• Data Analysis and Manuscript Preparation	Month 28-35
• Development of Final Report and Recommendations	Month 36
AIM #3: Develop and Pilot OSMP-T in Military Population	
• Develop Lesson Content Specific To Military	Month 22-24
• Obtain IRB approval form Walter Reed Medical Center	Month 24
• Screen Eligible Patients Discharged - Walter Reed	Month 29
• Enrollment and Baseline Assessment	Month 31-32
• Evaluations(immediate post, at 3 and 6 months)	Month 33-35
• Analysis and Recommendations	Month 36

Appendix 2: Biosketch for Katherine Frey

NAME Katherine Frey	POSITION TITLE Research Associate

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Virginia, College of Arts and Sciences	BA	1996	Biochemistry
Johns Hopkins University Bloomberg School of Public Health	MPH	2000	International Health

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

1996-1997	Peace Corps Volunteer *Community Health Project*	United States Peace Corps Moabi, Gabon
1997-1998	Peace Corps Volunteer Leader *Community Health Project*	United States Peace Corps Libreville, Gabon
2000-2005	Project Director National Study on Costs and Outcomes of Trauma Care	Johns Hopkins Bloomberg School of Public Health Baltimore, Maryland
2003-2005	Project Director Organization Financing and Delivery of Emergency Medical Services in the United States: Towards a Better Understanding of System Configuration	Johns Hopkins Bloomberg School of Public Health Baltimore, Maryland
2005-present	Project Director Guided Care Study	Johns Hopkins Bloomberg School of Public Health Baltimore, Maryland

PUBLICATIONS

MacKenzie EJ, Rivara FP, Jurkovich GJ, Nathens AB, Frey KP, Egleston BL, Salkever DS, Scharfstein DO. A national evaluation of the effect of trauma-center care on mortality. N Engl J Med. 2006 Jan 26;354(4):366-78.